EXHIBIT 5

An independent biomechanical evaluation of commercially available suburethral slings

J-L. PARIENTE[1]

[1]Centre d'Innovations Technologiques Biomatériaux, Hopital Pellegrin – Le Tripode Centre Hospitalo-Universitaire de Bordeaux, Place Amelie Raba Leon, 33076 Bordeaux cedex, France

Correspondence to: J-L Pariente
Email: jean-louis.pariente@chu-bordeaux.fr

Abstract

Many questions remain unanswered about the physical properties of suburethral slings. We report a laboratory based study that compared in vitro biomechanical characteristics of six slings used for stress incontinence: TVT (*Gynecare®-Ethicon®, USA*) IVS® (*Tyco Healthcare, USA*) Sparc® (*AMS, USA*) Uretex® (*Sofradim, France – distributed by BARD*) I-stop® (*CLmedical, France*) and Uratape® (*Mentor Porges, France*). Each sling was found to have quite different mechanical properties, varying from soft to hard tapes, and elastic to very stiff tapes, suggesting that different surgical procedures might benefit from different slings. In addition, an assessment was made of the amount of material shed by each tape during the testing procedure. This may have relevance to the clinical situation, where particles shed during surgical manipulation, may end up in the surrounding soft tissues with unpredictable impact on future success.

Keywords: biomechanical, suburethral slings, elasticity, rupture

Introduction

Tension free suburethral slings are commonly used for stress incontinence but many questions still remain. Why do they work? Are all slings equivalent? Which slings should we use? What are the optimal properties of materials? This study was set up to gain more experience of the physical properties of six commercially available suburethral slings, by performing a biomechanical evaluation of them.

The laboratory-based study compared *in vitro* biomechanical characteristics of six commercial slings used for stress incontinence: TVT; IVS®; Sparc®; Uretex®; I-stop®; and Uratape®.

Methodology & Results

The slings were studied macroscopically and microscopically by scanning electron microscopy to evaluate pore size. All of the slings are not pure biomaterials, but meshes with open pores that ideally allow macrophages to pass into the mesh matrix and fibrous tissue to grow inside the matrix. Electron micrographs of the meshes can be seen in Fig. 1, which also shows in magnification the effect of cutting each mesh.

Mechanical testing was performed with a 7 cm length sample (n=5) on an Instron® 4466 with a 500 Newtons sensor using the software SERIES IX-7 to program the setup (Figure 2). Materials

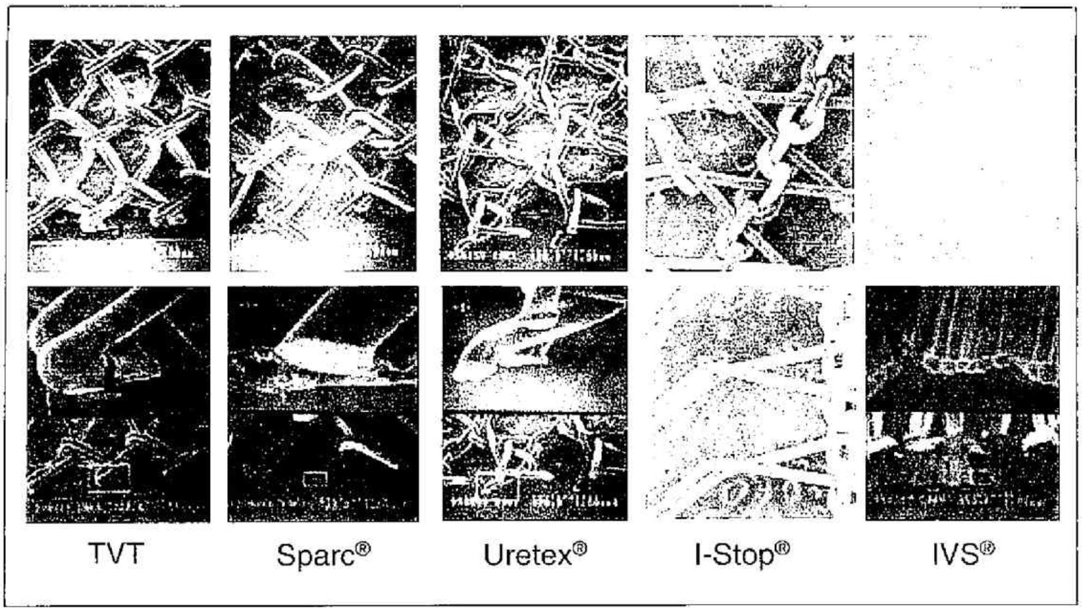

Figure 1. Meshes seen under EM

were tested at l0mm/min. Load-deformation data, elasticity modulus (Young modulus) and peak load (load at which rupture of sling occurs during traction) were recorded. Because these slings are cut from large rectangular blocks, small segments of material could be shed during and after deformation. Each sample was therefore weighed before and after a soft (0.01 kN) procedure to evaluate the particles released.

The Load deformation data are presented in Table 1. Two groups of responses are evident. The first group includes I-Stop®, IVS® and Uratape®; these meshes have a high elasticity modulus. The second group includes TVT, Sparc® and Uretex®, which each have a lower elasticity modulus, meaning they are elastic and supple. The elasticity modulus varies from a low of 4.31 (TVT) to a high or 41.99 (IVS®), a ratio of nearly 10:1. The maximum deformation attained also varies considerably, from 108% (Sparc®) to 31% (IVS®).

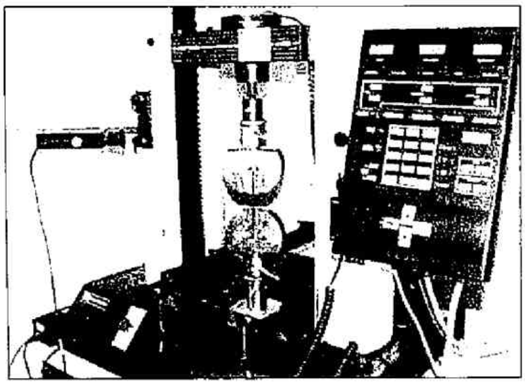

Figure 2. Instron® 4466 with 500 Newtons sensor Software SERIES IX-7

Figure 3 illustrates each different sling during traction and the results for the six tested devices expressed as load deformation curves. The first parts of the curves show the initial stiffness prior to reaching the elastic limits. This means the load deformation which allows an elastic reversal procedure for the biomaterials. The second part of each curve shows the rupture which occurs at peak load.

To evaluate the shedding of particles, each sample was weighed before and after a soft procedure, and the values range from 0 to 8.5 percent of initial weight. During surgical use, these particles are released in soft tissue and it is not possible to know where they go (Figure 4).

Table 1. Load deformation data

	Maximum deformation (%) of initial length	Maximum deformation (mm)	Young elasticity modulus (Mpa)	Peak Load (kN)
TVT	94.5±10.2	81.6±6.3	4.31±1.1	0.041±0.005
IVS®	31.4±1.8	24.61±5	41.99±14.3	0.035±0.005
Uretex®	61.36±11.8	43.72±7.9	5±0.78	0.047±0.013
Sparc®	108.24±11.5	77.2±7.1	5.35±0.86	0.038±0.011
I-Stop®	17.25±2.59	11.9±1.8	39.97±13.79	0.012±0.002
Uratape®	68.04±5.4	48.90±3.7	31.67±5.2	0.039±1.9

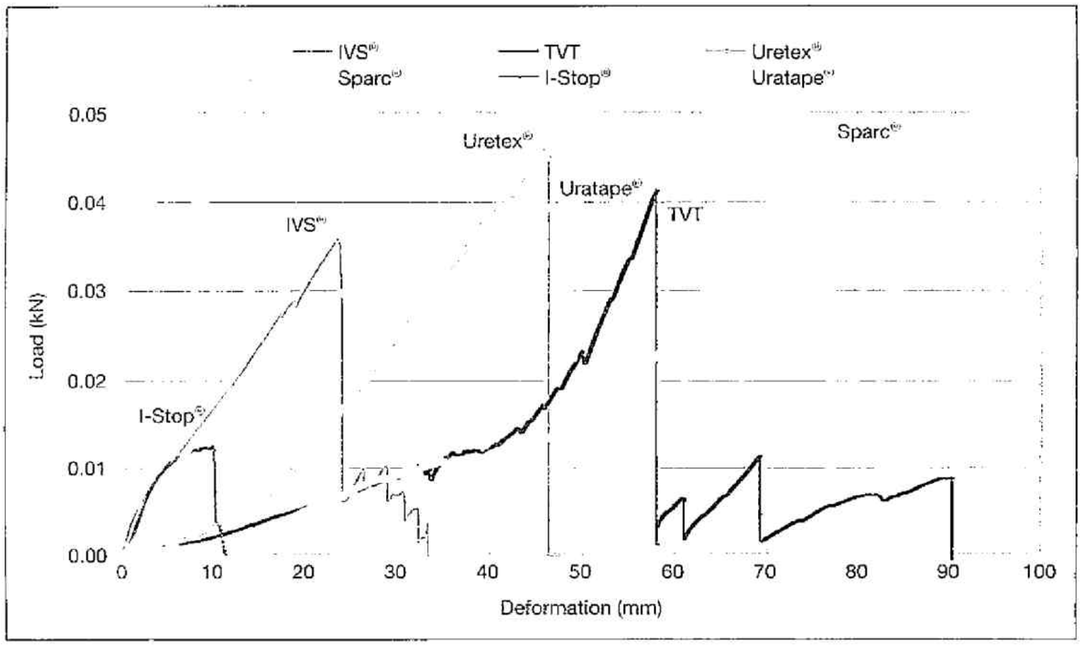

Figure 3. Load deformation curves

Conclusions

In conclusion, all the slings have very different mechanical properties and potentially very different clinical outcomes. The principal question to be answered therefore is which properties are really necessary: a soft or a hard tape, elastic or a very stiff one; and whether all of these suburethral slings can be used for the same application.

Clinical experience tells us that lower elasticity tapes such as TVT, Sparc® and Uretex® have comparable clinical outcomes, but the very high particle shedding of both Sparc® and TVT may be of significant long term clinical concern in some quarters.

Physicians should consider carefully which properties are really necessary for suburethral slings used for stress incontinence. Do we need

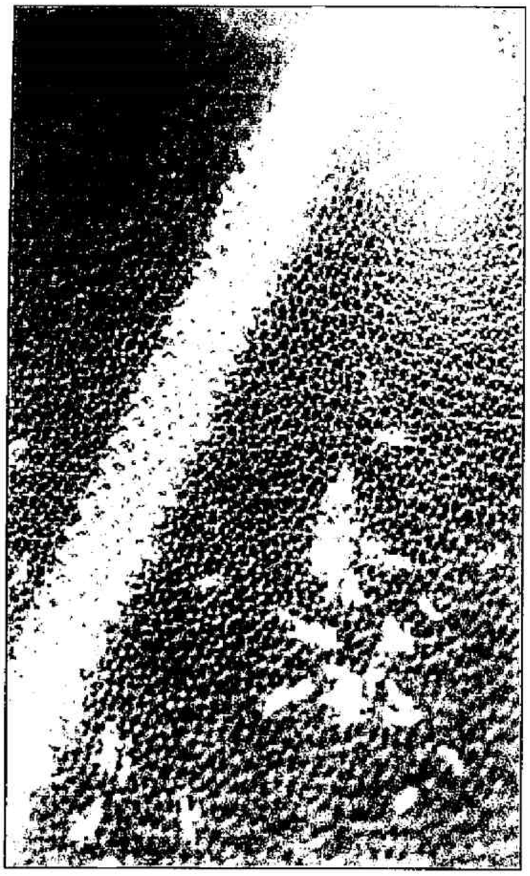

Figure 4. Particle shedding

Table 2. Particle release.

Sling Type	Particles released (Δpoids)
TVT	8.50%
IVS®	0.01%
Uretex®	1.05%
Sparc®	5.40%
I-Stop®	1.08%
Uratape®	0.01%

the same mesh for all applications? Different slings may suit different procedures, such as suburethral or transobturator; for normal pressure closure an elastic mesh may be needed, whilst a stiff one may be more suitable for low closure pressure. These questions require consideration of the physiology and pathophysiology of stress incontinence with regard to pressure and strength; a specification sheet for each device may be required before use. Further research is now underway in our laboratory to help answer these questions.